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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,419

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

04/17/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/595,419	Applicant(s) SCHIFFRIN ET AL.	
	Examiner ROBERT LANDSMAN	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/21/07</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Formal Matters

- A. The Preliminary Amendment filed 4/17/06 has been entered into the record.
- B. Claims 1-13 are pending and are the subject of this Office Action.

2. Information Disclosure Statement

- A. The German non-patent literature document cited on the 1449 filed 2/21/07 has been lined through since no English translation has been provided.

3. Claim Objections

- A. The syntax of claims 1, 9, 11, 12 and 13 can be improved by amending, for example, as follows -
 - 1. A nutritional composition comprising a lipid and a carbohydrate source and wherein the composition comprises the following:
 - (a) 40-80%...
 - (b) from 0.5 to 2.0...
 - (c) free glutamine...
- B. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites that the energy content is "at least 1.3 kcal/ml" whereas dependent claim 4 recites that the energy content can be below 1.3 kcal/ml (i.e. 1.2 – 1.3).
- C. Claim 10 is objected to since it recites "the use" instead of "the method."
- D. The syntax of claim 12 can be improved by amending the claim to read "...and/or radiotherapy in a patient comprising administering to said patient a nutritional..."

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4. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 9 and 11-13 can be read such that the entire weight of the composition can be made up only caesin and whey. However, the composition requires other components, including those recited in claim 7. It is suggested, for clarity, that Applicants amend claims 1, 9 and 11-13 to recite, as the last step, “and wherein the remainder of the composition comprises 40-80% by weight of casein and...”

The Examiner will accept other suggestions, or an explanation on the record

B. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “symptom” in claim 11 is used by the claim to mean an objective showing (which is called a “sign” of the disease, not “symptom”), while the accepted meaning is subjective, such as feeling nauseous or feeling tired. The term is indefinite because the specification does not clearly redefine the term. It is suggested that the “symptom” be replaced with “sign.”

C. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a conclusion step relating back to the preamble allowing one to determine when the method has been completed. In the instant situation, Applicants can overcome this rejection by reciting “administering to the patient an effective amount of a composition...”

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5. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perrin et al. (WO 02/083164) in view of Whyte et al. (WO 99/56758) and further in view of

The claims recite a nutritional composition comprising specific concentration and percentage ranges of casein, whey, TGF-b, energy and glutamine.

Perrin teach nutritional compositions comprising 5-30% of its energy from protein (page 6, lines 20-22), a lipid (page 6, lines 26-32) and 40-80% from a carbohydrate source (page 6, lines 33 - page 7, line 4). Page 9, Group "E" teaches whey and casein at a 1:1 ratio and which includes TGF-B2. Perrin teach that it has been found that TGF-B2 in casein retains its ability to be active in the digestive tract (page 4, line 17 – 5. line 18) and the amount of TGF-B2 is disclosed as being 0.5 to 3.5 ug. The 1:1 ratio would mean 50% casein and 50% whey, meeting the instant claim limitations. Perrin do not teach the addition of glutamine. Perrin also teach that the energy density is at least 50 kcal/ml (page 7, lines 6-8). The specification of Perrin is replete with examples of methods of producing these nutritional compositions. (e.g. pages 5-8)

However, Whyte do teach food compositions for changing the body composition and/or physical work capacity containing casein and growth factors (page 6, lines 1-6) and that the amino acid, glutamine, can also be included in the food (i.e. nutritional) composition as a supplement (page 7, lines 20-25).

Neither Perrin, nor Whyte teach the use of nutritional compositions for chemotherapy. However, Read et al. do teach nutritional compositions for the use in chemotherapy patients (Abstract; page 6, lines 6-10; page 7, line 30; claims 1 and 2, 8).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the glutamine as taught by Whyte in the method of Perrin since glutamine is taught, and is well known, to be a nutritional supplement. The goal of the instant invention is to provide a nutritional composition to patients in need. Glutamine is an amino acid required, inter alia, to build protein required

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for such things as muscle growth, which would be expected to be decreased in radiation and cancer patients.

Furthermore, it would have been obvious to use the combined composition of Perrin and Whyte to treat a chemotherapy patient as taught by Read since chemotherapy and radiation are known to cause, inter alia, mucositis. In fact, Read teach using casein and "milk product extract" (page 6, lines 11-19) as well as TGF-b (page 7, line 30).

Furthermore, a person of ordinary skill in the art would also be motivated to optimize conditions such as dosage and pH. MPEP 2144.05 states:

[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 454, 105 USPQ 223,235, (CCPA 1955)

6. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647